Empowering Adults with Diabetes: Achieving Self-Management Success Through Data-Driven Behavior Change, Pilot Randomized Control Trial

NCT06848361

Informed Consent Form

09/11/2026

University of Pittsburgh

Department of Medicine
School of Medicine

1218 Scaife Hall
3550 Terrace Street
Pittsburgh, PA 15261
412-648-9636

Consent to Participate in a Research Study

MPowerHub Pilot Trial

Study Principal Investigators:

Ann-Marie Rosland, MD, MS
Associate Professor of Internal Medicine,
Director, Caring for Complex Chronic Conditions Research Center
University of Pittsburgh
Email: roslandam@pitt.edu

Carissa A. Low, PhD
Associate Professor of Medicine, Psychology, & Bioinformatics,
Director, Mobile Sensing + Health Institute
University of Pittsburgh
Email: lowca@upmc.edu

Funding: National Institute of Diabetes and Digestive and Kidney Diseases

Summary of Research

- The purpose of this study is to find out if a mobile phone application called MPowerHub can help people with type 2 diabetes manage their diabetes and achieve blood sugar goals.
- The risks in participating in this study are minimal.
- Participating in this study is voluntary.
- If you agree to take part in this study, your involvement will last four to six months.
- You'll be placed into one of three groups: the MPowerHub intervention group, which involves using the MPowerHub app while wearing both a continuous glucose monitor (CGM) and an activity tracker (Fitbit), the CGM-only group, or the Fitbit-only group.
- You'll be asked to complete two surveys and have a visit with a diabetes care and education specialist (DCES).
- You may be asked to take part in an additional user feedback interview at the end of the study to learn about your experiences.
- You may receive up to $125 for participating in this study.

What is the purpose of this study?

You've probably noticed that there are a lot of different devices that people can use to monitor their health. Fitbits, used to track activity and sleep, are one example of this kind of device. Another example is continuous glucose monitors or CGMs for people with diabetes, which are used to track blood sugar levels.

The purpose of this research study is to test a new mobile phone app called MPowerHub. MPowerHub combines CGM information with information from Fitbits, as well as information about health-related behaviors that people enter themselves. Having all this information in one place is designed to make it easier to see patterns and relationships between daily activities and blood sugar levels. Understanding these relationships might help people with diabetes make decisions and set goals for diabetes management.

This mobile medical app is considered a medical device. While it has not been cleared by the U.S. Food and Drug Administration (FDA) it is considered a low-risk category of device that does not need prior approval. The institutional review board of the University of Pittsburgh has approved its use in this study.

How do I know if I qualify to be in this study?

You are qualified to join this study if you

- are between 25 and 75 years of age
- received care at a UPMC Health System outpatient clinic during the last 12 months
- were told by a doctor or nurse that you have type 2 diabetes mellitus
- had a A1c value of 7.5% or higher during the past 6 months
- are taking at least one non-insulin diabetes medication prescribed by your doctor
- own or have access to a smartphone that can access an internet website

What will happen if I join this study?

Study Group Assignment

After you enroll in the study, you will be randomly assigned to 1 of 3 study groups:

- MPowerHub intervention: You have a 50% chance of being assigned to this group.
- CGM only: You have a 25% chance of being assigned to this group.
- Fitbit only: You have a 25% chance of being assigned to this group.

Baseline Survey

You'll complete a brief survey, which can be administered virtually on Zoom or taken independently on your electronic device. We will ask you about

- your physical and emotional health and health habits related to diabetes,
- what it's like for you to live with type 2 diabetes,
- your experience with and what you think about using wearable monitors like CGMs and Fitbits,
- how comfortable you are with using health technology during daily life, and
- how much you know about health and health-related behaviors.

App Download Visit

A clinical research coordinator will meet with you in-person or over Zoom to help you download the mobile phone apps that you need for the study.

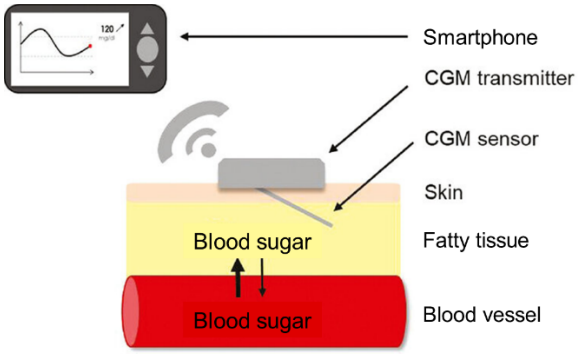
- MPowerHub intervention: Downloading MPowerHub app, Dexcom G7 app, and Google Health app
- CGM only: Downloading Dexcom G7 app
- Fitbit only: Downloading Google Health app

DCES Visit

Then you'll meet with a Diabetes Care and Education Specialist (DCES) and a member of the study team for about 60-90 minutes in person or virtually on Zoom. The following activities will happen during this meeting, depending on your group assignment:

If you are assigned to the **MPowerHub** group,

- **You'll get your CGM device** (see picture below). We'll show you how to use it and help you set it up. The CGM will check your blood sugar levels regularly throughout the day and night. The CGM is a disposable device that includes an integrated sensor and transmitter. The slim sensor wire is inserted under the skin and is connected to a small transmitter that automatically sends information to a smart device. The CGM is inserted on the back of the arm and held in place with an adhesive patch. We'll help you install an app on your phone to permit wireless syncing of your CGM data. You'll wear your CGM at all times except when you need to replace the sensor (about every 10 days). We'll give you additional sensors and instructions for replacing the sensor. The CGMs used in this study were donated by Dexcom, Inc. Please refer to the Dexcom Privacy Policy for more information on using this device: https://www.dexcom.com/legal/privacy-policy.





Dexcom.com

- **You'll get your Fitbit activity tracker** and instructions on how to use it. You wear the Fitbit like a wristwatch, and you'll use it to track your activity and sleep levels. We'll ask you wear your Fitbit at all times except when you need to charge it (about once every 4-5 days). It's waterproof, so you won't have to worry about getting it wet. We'll help you install the Google Health app app on your phone to permit wireless syncing of your data. If you own and use a similar Fitbit that you have connected to a personal Google Health account, you'll have the option to use it for the study.
- **We'll introduce you to the MPowerHub app** and show you how to access it on your smartphone. You'll learn how to use MPowerHub to view your CGM and Fitbit data and answer daily questions related to your diabetes self-management. Also, the DCES will talk to you about diabetes self-management and goal setting strategies and show you how to use MPowerHub to set goals and track your progress over time.

If you are assigned to the **CGM only** group,

- **You will get your CGM device** as described above, and a member of the study team will help you set it up. You'll wear your CGM at all times except when you need to replace the sensor (about every 10 days). We'll give you additional sensors and instructions for replacing the sensor.

If you are assigned to the **Fitbit only** group,

- **You'll get your Fitbit** and instructions on how to use it as described above. We'll ask you wear your Fitbit at all times except when you need to charge it (about once every 4-5 days). We'll help you install the Google Health app on your phone to permit wireless syncing of your data. If you own and use a similar Fitbit that you have connected to a personal Google Health account, you'll have the option to use it for the study.

Monitoring Period

The study duration for all three groups is about 3 to 4 months. We will give you our study team contact information if you have any questions or difficulties with the apps or devices during the monitoring period. In addition, a study team member will offer to contact you approximately 10 days after you start the monitoring period, and the DCES will offer to contact you about two weeks after you start the monitoring period to follow up on the diabetes education session discussion and study devices. At the end of the monitoring period, we will deactivate the CGM and Fitbit accounts that were created for the study, and help you remove the apps from your phone.

Follow Up Survey Visit

At the end of the 3- to 4-month monitoring period, a study team member will contact you to schedule your second survey in person or virtually on Zoom. We will ask you the same questions as in the baseline survey, with additional questions on the usability of the apps and devices you used.

User Feedback Interviews

We may ask you to participate in a user feedback interview. The reason we are doing the user feedback interviews is to give you a chance to tell us what it was like being a participant in this research study. The interviewer will ask you to describe your overall experience participating in the study,

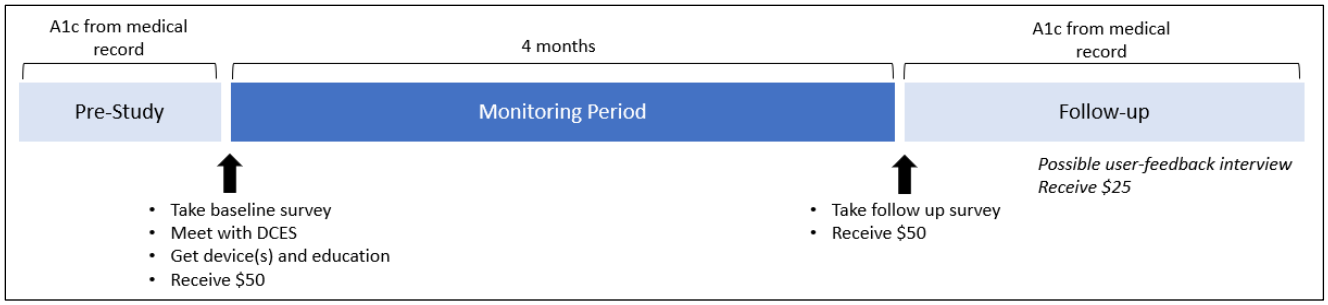
- your thoughts on getting started and participating in the initial study session,
- your day-to-day experience using MPowerHub, the CGM and/or the Fitbit, and
- your thoughts on how the study impacted your diabetes management.

With your permission, we will record the interview.

Other Study Activities

Because we are interested in whether MPowerHub affects blood sugar levels, after you have finished monitoring, the study team will need to obtain an updated A1c. First, the study team will check your medical record for an updated A1c (see *HIPAA Authorization for Disclosure of Protected Health Information* below). If one is not documented, we will ask if you intend to have a lab drawn within the study period and we will use that value for study purposes once it is available. If you do not, the study team will help you measure your A1c using a fingerstick hemoglobin A1c meter. It works just like a lancet to check blood sugar. This can be a self-administered test or completed by a study staff member. If self-administered, we will mail you an A1c test kit that you can use at home. We will then schedule a Zoom call with you to retrieve the results in real time.

Study Timeline



What are the risks of being in this study?

Possible risks of joining the study may differ depending on your group assignment to MPowerHub, CGM only or Fitbit only. The table below lists possible risks for each group.

Possible Risks of Participating in this Study	MPowerHub	CGM	Fitbit
High or low blood sugars: The CGM being used for this study is extremely accurate. However, not using the CGM as directed could result in you missing an episode of severe low or high blood sugar. Contact your healthcare provider if you have a very low or very high blood sugar episode. We will not be monitoring information from your CGM in real-time, so we will not be able to alert you if your blood sugar is too low or too high.	X	X	
CGM sensor: It's uncommon, but inserting the sensor can cause infection, bleeding, or pain, and wearing the adhesive patch can irritate your skin. There is a remote chance a sensor wire could break or detach and remain under your skin. Contact the study DCES directly if you have problems with your CGM.	X	X	
Continuous blood sugar monitoring: Some people may begin to worry more about how diabetes affects their health if they have increased access to information about their blood sugar levels, which might not always be at goal. Contact the study DCES directly if you have serious concerns about your health related to diabetes.	X	X	
Activity tracking device: Wearing the activity tracker may be uncomfortable for some people who are not accustomed to wearing a wristwatch and/or may cause skin irritation. Contact the study team if you have problems with your activity tracker.	X		X
Study surveys and interviews: Some people don't feel comfortable with being interviewed or with being asked to answer questions that are personal in nature. If you begin to feel uncomfortable during your interview, tell your interviewer right away about how you are feeling.	X	X	X
Confidentiality: There is a rare risk that a breach of confidentiality may occur. We will do everything we can to prevent this from happening. If you think the confidentiality of your research information has been breached, contact either of the two investigators listed on the first page of this form.	X	X	X

There may be risks or discomforts that we don't know about now. We will tell you about any important new information we learn that may relate to your willingness to continue participating in this study.

Will being in this study help me in any way?

You may benefit in several ways from participating in this study:

- You may have more information about you daily blood sugar and activity trends
- You may also benefit by
    - better understanding how your blood sugar levels relate to your physical activity
    - learning how to set daily health goals
    - learning about diabetes and diabetes management
    - worrying less about diabetes
    - feeling more in control of your health

There is no guarantee that you will receive these benefits. However, your participation in this study may help others understand how to help people manage diabetes and stay healthy.

Who will see my information? How will you keep it private?

We will do everything we can to protect the privacy of your personal information. But confidentiality cannot be guaranteed. We will work hard to prevent a loss of privacy. We must keep the research records confidential following federal, state, and local laws. All research data collected in this study will be stored according to the privacy and security guidelines set by the U.S. Code of Federal Regulations.

We will assign you a study ID number. Your research information will be labeled with your study ID number and not with your name. Neither your name nor any other identifying information will appear anywhere on your research data. We will permanently delete your interview recording after it has been transcribed and reviewed for accuracy. Any personally identifying information will be removed from the transcript. The information linking your study ID and your name is kept separate from your research records. The only people who may look at your identifiable information are:

- The investigators listed on the first page of this form and other members of the study team
- Authorized representatives of the University of Pittsburgh Office of Research Protections. They may monitor the conduct of this study. We must keep research records for 7 years after the final project report.
- The study sponsor, the National Institute of Diabetes and Digestive and Kidney Diseases/National Institutes of Health
- The CGM and activity tracker and associated app companies (Dexcom, Fitbit, and Google Health) may see information specific to their devices and associated apps. The devices and associated apps used as part of this study may collect information you enter during installation and use (email, type of mobile device used) and health data (e.g., blood glucose values and steps). Agreeing to the Privacy policies of the devices/apps when they are installed gives consent, or allows, the devices/apps to collect this information. Privacy policies can be accessed at https://www.dexcom.com/legal/privacy-policy & https://support.google.com/product-documentation/answer/14815921 respectively.
- We also will inform your primary care provider and/or relevant specialists that you are participating in this study.

We will keep printed copies of all research data and signed consent forms in a locked file cabinet, behind a locked door in a secured office located on the University of Pittsburgh campus. All electronic files, including information from MPowerHub (CGM data, Fitbit data, information you enter yourself) will be stored in folders and servers that only authorized members of the study team can access. We will do everything possible to protect your privacy, but confidentiality during internet, email, and text messaging communication activities cannot be guaranteed, and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study.

Study researchers will analyze the data collected from this study. If the results of this study are reported in journals or at professional meetings, you will not be identified. No information that can be used to identify you will be released or published unless required by law. Your study data may be shared with researchers doing similar research, but only after all identifying information has been removed.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. This website can be searched at any time. In addition, de-identified information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

HIPAA Authorization for Disclosure of Protected Health Information

As part of this research study, we are requesting your authorization or permission to review your medical records to gather information about diabetes management from the past year and during the study. Information collected from electronic medical records will only be related to the research study. The information is needed to determine whether you meet the conditions for participation in this study and to compare your earlier test results to the findings from this study. The information may include diagnoses, demographic information, vital signs, prescriptions, past medical history, diagnostic procedures, results from routine blood work, and visits with diabetes providers. As part of this research study, some information that we obtain from you will be placed into your medical records, including that you are participating in this study. This identifiable medical record information will be made available to members of the research team for an indefinite period of time. The U.S. Food and Drug Administration (FDA) may also access research and personal health information records for the purpose of monitoring the study.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know:

- The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.
- The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.

- The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Will it cost me anything to join this study?

There will be no cost to you or your insurance provider if you decide to participate in this study.

Will I be paid for being in this study?

If you join this study, you will be paid through the University payment system. We'll pay you $50 at the beginning of the study after you have completed the baseline study visit and survey and $50 at the end of the study after you are finished monitoring and have completed the second survey. If we ask you to participate in an additional user-feedback interview, we'll pay you another $25 (possible total of $125). If you are assigned to the MPowerHub or Fitbit group, you'll also be allowed to keep the Fitbit we gave you when you joined the study.

Before the payment can be activated, a member of the study team will ask you for some personal information including your address and social security number. This information will be used for tax purposes only. All payments received for participating in a research study are taxable income, regardless of the amount. If a participant is paid $600 or more in a calendar year from one organization, that organization is required by law to file a Form 1099 – Miscellaneous with the IRS and give a copy to the taxpayer. If you don't want to share your social security number, we will pay you a lesser amount with 24% income tax withheld. So, you would only receive 76% of the expected payment.

What happens if I get sick or hurt while I am in this study?

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not waive any rights by signing this form.

What are the alternatives to being in this study?

You do not have join this study or any other research study offered to you by your healthcare provider or other staff member at the clinic where you receive care. You may choose not to be in this study and continue your current/usual care for diabetes.

What happens if I say yes but change my mind later?

You can quit the study at any time, even after signing this form. To quit the study, please contact Dr. Ann-Marie Rosland (roslandam@pitt.edu). We will keep any research information you gave us before you decided to quit.

Can I be taken out of the study even if I want to continue?

The researchers may need to take you out of the study without your consent for the following reasons:

- The study team thinks it will be in your best interest not to be in the study
- The study is suspended or canceled
- You exhibit any threatening, violent or harassing behavior toward study staff
- You are put in jail or placed on parole while you are taking part in the study
- You become pregnant while you are taking part in the study

Consent to Participate in this Research Study

Voluntary Consent

Taking part in this research study is completely voluntary. You don't have to participate if you don't want to. Your decision of whether or not to join this study will not affect the services you receive from UPMC Health System. You can sign this form and decide later not to participate. If you leave the study before it is finished, you will not be penalized, and you will not lose any benefits you are entitled to receive. Before signing, be sure you can answer "yes" to the statements below.

The information printed on this form has been explained to me. All of my current questions have been answered. I understand the following:

- The risks and benefits of joining this study.
- I may ask questions or voice concerns or complaints about any part of this study at any time.
- A member of the research team will answer any questions, concerns or complaints I might have.
- I may ask that my questions, concerns or complaints be addressed by one of the investigators on the first page of this form.
- If I have concerns about the study, I can contact the Human Subjects Protection Advocate of the Institutional Review Board by calling the University of Pittsburgh at 1-866-212-2668.

Research Participant Signature

By signing this form, I agree to participate in this research study and provide my authorization to share my medical records with the research team. I understand that I will receive a copy of this form once I sign it.

Participant's Signature	Date
Participant's Printed Name	Phone Number

Principle Investigator (or Designee) - Certificate of Informed Consent

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. I further certify that no research component of this protocol was begun until after this consent form was signed. Any questions the individual(s) have about this study have been answered, and a member of the research team will always be available to address future questions, concerns or complaints as they arise.

Signature of Person Obtaining Consent	Date
Printed Name of Person Obtaining Consent	Role in Study